

# Notice of Allowability

Application No.

10/743,529

Examiner

EBENEZER SACKEY

Applicant(s)

SPEIRS ET AL.

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1626

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to preliminary amendment filed 06/28/04.
2. ☒ The allowed claim(s) is/are claims 29-34 now claims 1-6 respectively.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 06/28/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 08/05/04
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

JAMES O. WILSON  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dennis Shelton on 08/05/04.

The application has been amended as follows:

#### **IN THE CLAIMS:**

Cancel claims 1, 18-23 and 27-28 without prejudice.

#### **NEW CLAIMS 29-34:**

29. A method of treatment of a patient having an endobronchial infection comprising administering to the patient for inhalation a nebulized unit dose of 4.0 ml or less of an aqueous solution comprising from about 60 to about 200 mg/ml of tobramycin in a physiologically acceptable carrier for a duration of nebulization less than about 10 minutes, using an inhalation device having a rate of aerosol output of not less than about 4  $\mu$ l/sec, that releases at least about 75% of the loaded dose, and that produces aerosol particles having particle sizes between about 1 $\mu$ m to about 5 $\mu$ m.

30. A method of claim 29 wherein the inhalation device has a rate of aerosol output of not less than about 5 $\mu$ m/sec.

31. A method of claim 29 wherein the inhalation device has a rate of aerosol output of not less than about 8  $\mu$ m/sec.

32. A method of claim 29 wherein the inhalation device releases at least about 80 percent of the loaded dose.

33. A method of claim 29 wherein the inhalation device releases at least about 85 percent of the loaded dose.

34. A method of the treatment of a patient having an endobronchial infection comprising administering to the patient for inhalation a nebulized unit dose of 3.5 ml or less of an aqueous solution comprising from about 90 to 150 mg/ml of tobramycin in a physiologically acceptable carrier for a duration of nebulization less than about 6 minutes, using an inhalation device having a rate of aerosol output of not less than about 4  $\mu$ l/sec, that releases at least about 75% of the loaded dose, and that produces aerosol particles having a particle size of about 1 $\mu$  to about 5 $\mu$ .

### ***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance: applicants claim a method of the treatment of a patient having an endobronchial infection. The novel features of this invention reside in requiring 10 minutes or less for duration of nebulization, with an inhalation device having a rate of aerosol output of not less than 4  $\mu$ l/sec that releases at least 75% of the loaded dose and that produces particle sizes of between about 1 $\mu$  to about 5  $\mu$ . The prior art of record, which is U.S. Patent number 5,508,269, discloses delivery of less than 50% of the loaded dose and a negative teaching to not use vials of less than 5 ml. Applicant's data in the specification supports the advantages of the problems over the prior art. Additionally, the instant

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invention solves the prior art problems of toxicity and stability. Such novel features are neither taught nor anticipated by the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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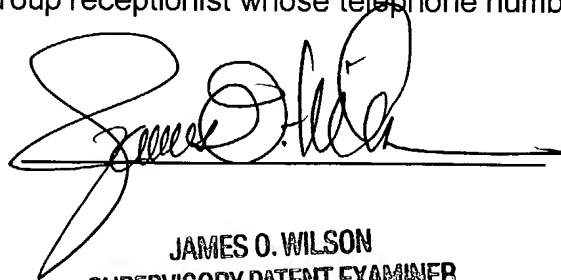
Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (703) 305-6889. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

EOS  
August 6, 2004

**THURMAN K. PAGE, M.A., J.D.**  
**SUPERVISORY PATENT EXAMINER**



**JAMES O. WILSON**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**